COMMITTEE ON HUMAN RESEARCH
INITIAL SUBCOMMITTEE REVIEW APPLICATION
COVER PAGE

PRINCIPAL INVESTIGATOR (UCSF Faculty)
(Name & Degree) David Rempel, M.D.
Mailing Address
(Campus) SFGH, Bldg 30, 5th Floor
University
Title Asst Clin Prof
Dept. Medicine
Phone
Number 237-7400
Is P.I. Sponsor/
Advisor Only? No

CO-P.I.
(Name & Degree)
Mailing Address
(Campus)
University
Title
Dept.
Phone
Number
SUBMISSION
DATE

PROJECT
TITLE The Relationship of Tobacco Exposure to Semen Biomarkers

EXPEDITED REVIEW CATEGORY NUMBER ____ (from PART V-B of the *UCSF Guidelines for Research Involving Human Subjects*, October 1987)

NAMES/DEGREES OF ALL OTHER INVESTIGATORS:
Jack Gerson, Ph.D
Andrew Wyrobek, Ph.D
Laura Fenster, Ph.D
David Katz, Ph.D
Neil Benowitz, Ph.D

HISTORY OF THIS PROJECT:
Previous CHR approval # H5534-05763-01
___ New
___ Modification (Highlight changes in protocol.)
_X_ Renewal Expiration Date 7/15/91

PROCEDURES (List all procedures to be done for purposes of the study): Saliva and semen analysis by gas chromatography -- mass spectroscopy for nicotine and cotinine.

SUBJECTS (Discuss in protocol. If exact number is not known, please estimate.):
Experimental Subjects:
Number (This Year) 185 (Total for Study) 220
Source(s) Kaiser subscribers
Reimbursement
Controls/Normals:
Number (This Year) (Total for Study)
Source(s)
Reimbursement

Special Subject Populations (Check and discuss in protocol. See Appendix G of *CHR Guidelines*.)
___AIDS/HIV-Infected Individuals
___Minors ___Fetuses, Pregnant Women
___Those Unable to Speak or Read English
___Those Unable to Consent for Themselves
___Prisoners

SITE (Check and discuss in protocol):
___Parnassus ___VAMC _X_SFGH ___MtZION
___Other UCSF site
Other

FUNDING:
Will this study be funded? _X_Yes ___No ___Pending--
___Federal ___Pharmaceutical/Device Co. ___Other
Agency/Sponsor Name (Grant/Contract #, if known):
Tobacco Related Disease Research Program #RT 500

David Rempel 6-15-91
PRINCIPAL INVESTIGATOR'S SIGNATURE & DATE

(See reverse side for instructions and format.)

rev. 1/91

2025794509

COMMITTEE ON HUMAN RESEARCH
INSTRUCTIONS FOR INITIAL SUBCOMMITTEE REVIEW APPLICATION

Please submit five (5) identical, collated sets of the following:

a) CHR INITIAL SUBCOMMITTEE REVIEW APPLICATION COVER PAGE (signed by principal investigator);
b) PROTOCOL WRITTEN ACCORDING TO INITIAL SUBCOMMITTEE REVIEW APPLICATON FORMAT (*within three-page limit*);
c) ALL INFORMATION SHEETS AND/OR CONSENT FORMS; and
d) ALL SPECIAL ATTACHMENTS (i.e., questionnaires, interview guides, letters of support).

If a cover letter is included, please attach a copy to all five sets of materials.

For detailed information regarding the Initial Subcommittee Review Application, standard consent form format, and special requirements and attachments, please refer to the *Guidelines for Research Involving Human Subjects at the University of California, San Francisco* (October 1987). A copy of these guidelines, all current forms, and information regarding submission and review schedules can be obtained in person at the Committee on Human Research, suite 11, Laurel Heights Campus, or by calling 476-1814.

Please note: It takes approximately 4 to 6 weeks to complete the review process of an Initial Subcommittee Review Application. However, if the expedited review category is #8 (see page 18 of the guidelines), the process may be completed in less than two weeks. Factors such as University holidAy periods, summer vacation schedules, and major granting agency deadlines, when the volume of applications submitted to the CHR increases greatly, may lengthen the time to complete the review process and should be taken into consideration.

Submit applications to: Committee on Human Research (CHR)
Box 0962
UCSF
San Francisco, CA 94143-0962

INITIAL SUBCOMMITTEE REVIEW APPLICATION FORMAT

1. STUDY AIM, BACKGROUND, AND DESIGN
2. SUBJECT POPULATION; INCLUSION/EXCLUSION CRITERIA, USE OF SPECIAL SUBJECT GROUPS, AND METHODS OF ACCESS
3. PROCEDURES TO BE DONE FOR PURPOSES OF THE STUDY
4. RISKS: POTENTIAL DISCOMFORTS AND RISKS, INCLUDING POSSIBLE LOSS OF CONFIDENTIALITY, TO SUBJECTS, AND THE METHODS OF MINIMIZING THESE RISKS
5. BENEFITS; POTENTIAL DIRECT BENEFITS TO SUBJECTS AND GENERAL BENEFITS TO SUBJECT GROUP, MEDICAL SCIENCE, AND/OR SOCIETY
6. CONSENT PROCESS AND DOCUMENTATION
7. QUALIFICATIONS OF INVESTIGATORS (brief paragraph only; do not submit curricula vitae)

Please note: The application, excluding CHR Cover Page and attachments, may not exceed three pages in length.

1/91